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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,832

06/13/2005

Pia Norup Nielsen

P68468US1

5175

136 7590 06/12/2008

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,832	Applicant(s) NIELSEN, PIA NORUP	
	Examiner Lynne Anderson	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6 March 2008 have been fully considered but they are not persuasive.
2. In response to applicant's argument that Nilsson fails to disclose a catheter adapted for intermittent catheterization, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The catheter element disclosed by Nilsson is fully capable of being removed and reinserted, and therefore is adapted for intermittent catheterization.
3. In response to the applicant's argument that there is no suggestion in Nilsson of the use of any drugs to treat patients with incontinence, it is noted that Martan and Ottoboni teach the intravaginal introduction of drugs for the treatment of incontinence. Since Nilsson teaches the use of a catheter to introduce a drug (i.e. a hormone preparation) intravaginally, it would be obvious to one of ordinary skill in the art to use the catheter device of Nilsson to introduce the drugs taught by Martan and Ottoboni for the purpose of treating incontinence.
4. In response to the applicant's argument that Hunter fails to teach delivering the compositions disclosed by the applicants, it is noted that Hunter is relied upon to teach placement of the composition on the outer surface of the catheter for delivery, and not for the teaching of the specific compositions to be delivered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Nilsson (WO 91/00074).

7. Nilsson discloses a kit comprising a device for urinary catheterization, as shown in figure 1, and a pharmaceutically active composition comprising a hormone, as described on page 8, lines 3-8. The device comprises a catheter element 10 adapted to be inserted into the urethra of a female, as disclosed on page 1, lines 5-12. The pharmaceutically active agent is provided in a discrete unit dose at the tip 14 of the catheter, as shown in figure 1. The catheter element 10 is fully capable of being removed and reinserted, and therefore is adapted for intermittent catheterization.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 6-14, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246).

10. With respect to claims 1-2 and 14, Nilsson discloses all aspects of the claimed invention with the exception of the pharmaceutically active composition being located on the outer surface of the catheter. Nilsson discloses a device comprising a urinary catheter element 10, as shown in figure 1. The catheter element 10 is fully capable of being removed and reinserted, and therefore is adapted for intermittent catheterization. The catheter 10 has a pharmaceutically active composition comprising a hormone disposed therein, as disclosed on page 8, lines 3-8. The pharmaceutically active composition is delivered to the urinary tract during catheterization, as disclosed on page 8, lines 9-16.

11. Hunter teaches the application of a pharmaceutically active composition on the outer surface of a urinary catheter, as disclosed on page 2, lines 23-24. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the pharmaceutically active composition on the outer surface of the urinary catheter of Nilsson, since Hunter teaches the predictable result of a pharmaceutically active composition being delivered to the user when the composition is coated on the surface of the catheter.

12. With respect to claim 3, Hunter discloses a major part of the composition being present on the outer surface of the catheter. With respect to the device being provided in a sealed package, it is well-known in the art to provide medical devices in a sealed package prior to use to prevent contamination of a device prior to insertion into the body of a patient. It would therefore be obvious to one of ordinary skill in the art at the time of invention to seal the device of Nilsson in a package to prevent contamination.

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13. With respect to claim 4, Hunter discloses the composition is coated over the length of the catheter element.

14. With respect to claim 6, Nilsson discloses the catheter element is a female catheter, as disclosed on page 1, lines 5-8.

15. With respect to claims 7 and 9-10, Hunter discloses a hydrophilic coating in which the pharmaceutically active composition is impregnated, as described on page 2, lines 23-24.

16. With respect to claim 8, Hunter discloses a polymeric coating, as described on page 4, lines 17-18.

17. With respect to claim 11, Nilsson discloses depressions 15 on the outer surface, as shown in figure 1, which are adapted to hold the pharmaceutically active agent, as described on page 8, lines 3-8.

18. With respect to claims 12 and 13, Hunter discloses the coating is a lubricating gel, as described on page 2, lines 9-10.

19. With respect to claims 21-26, Nilsson discloses the use of the device to perform the method of treating a female suffering from incontinence, as disclosed on page 1, lines 5-29.

20. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246), and further in view of Martan et al. ("Ultrasound imaging...", Ceska Gynekol, Jan. 1999).

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21. Nilsson, as modified by Hunter, discloses all aspects of the claimed invention with the exception of the hormone being oestriol or oestrogen. Martan teaches the use of oestriol and oestrogen in the treatment of females suffering from incontinence (see Abstract). The oestriol or oestrogen is administered intravaginally. It would therefore be obvious to one of ordinary skill in the art at the time of invention to use oestriol or oestrogen as the hormone in the device of Nilsson, as taught by Martan, to effectively treat incontinence.

22. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246), and further in view of Ottoboni et al. (6,039,967).

23. Nilsson, as modified by Hunter, discloses all aspects of the claimed invention with the exception of the pharmaceutically active composition being an efferent blocking agent comprising oxybutynin. Ottoboni teaches the use of oxybutynin in the treatment of incontinence, as disclosed in column 5, lines 14-16. The oxybutynin is delivered to the urinary tract by a catheter coated with the composition, as disclosed in column 7, Example 7. It would therefore be obvious to one of ordinary skill in the art at the time of invention to use oxybutynin as the pharmaceutically active composition of Nilsson, as taught by Ottoboni, to effectively treat incontinence.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761